

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

JAZZ PHARMACEUTICALS, INC.,)	
)	
)	
Plaintiff,)	CIVIL ACTION NO.:
)	2:10-cv-06108 (ES) (CLW)
vs.)	(consolidated)
)	
ROXANE LABORATORIES, INC.,)	
)	
Defendant,)	
)	

**ROXANE LABORATORIES, INC.’S NOTICE OF SUPPLEMENTAL EVIDENCE IN
SUPPORT OF ITS CLAIM CONSTRUCTIONS**

Roxane submits this Notice of Supplemental Evidence to bring to the Court’s attention new intrinsic evidence from the prosecution histories of continuation applications of Jazz’s patents, not previously available, which support Roxane’s constructions and contradict arguments previously made by Jazz. These intrinsic evidence statements are relevant to two claim terms that the Court is currently considering: (1) “about” and (2) “dose.”

**I. CLAIM TERMS NEED TO BE CONSTRUED CONSISTENTLY
THROUGHOUT THE ENTIRE PATENT FAMILY**

As discussed in Roxane’s Opening Markman Brief, (D.I. 77), Federal Circuit authority requires the Court to construe claim terms based on the intrinsic evidence and provides that terms be given consistent meanings throughout the claims of a patent and its family. (*See* D.I. 77 at 2 citing *Vitronics Corp. v. Conceptiontronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*)). This rule extends to the consideration of statements made by a patent applicant regarding a term’s proper construction in

later-filed continuation applications. (*See, e.g.*, D.I. 77 at 13 (discussing disavowal made regarding term “prescription drug” in a later-filed continuation application).)

II. THE CLAIM TERM “ABOUT”

Roxane files this Notice to advise the Court that in remarks filed on August 24, 2012 in a continuation application in the ‘431 patent family, Jazz made unequivocal statements regarding the proper construction of the term “about.” (*See* Ex. A, August 24, 2012 Amendment & Response under 37 C.F.R. § 1.111 filed in U.S. Patent Application No. 13/446,892 at 6-8.)

These clear statements support Roxane’s proposed construction that “about” should be construed as “20% of the number modified in the appropriate direction(s).” Jazz has now advocated the same construction for this term in its own intrinsic evidence in order to distinguish a prior-art reference. Specifically, in the August 24, 2012 Amendment & Response (Ex. A), Jazz argued against a Patent Examiner rejection stating:

The Examiner contends that the individual doses disclosed by Broughton et al., 1.5-2.25 g, followed by 1.0-1.5 g, would “reasonably be considered to be ‘about 4.5 to about 10 grams’ or ‘about 3 to about 10 grams,’ absent an explicit definition provided by Applicant as to the amount of variation tolerated by the term ‘about’ as used in the instant claims.” Applicants respectfully disagree.

At paragraph [0014] of the published specification, it is disclosed “As used herein, the term ‘about’ generally means within about 10-20%.” “As used herein” is manifestly a reference to the specification, including the claims. Even applying the 205% variation to 3.0 g, the lowest single dose recited by the present claims, does not cause overlap with the highest single dose disclosed by Broughton et al., 2.25 g, which is only to be given once. In contrast, claim 2 recites administering a dose of about 3.0 grams of GHB at least twice. Applying the 20% variation to claim 1 yields a minimum single dose of 3.4 grams, a dose that is 50% above the maximum single dose disclosed by Broughton et al.

(Ex. A. at 6-7 (emphasis in original), *cf.* D.I. 77 at 6-7.)

In other words, Jazz has adopted before the Patent Office (i) that the same passage recited in the RoxaneMarkman briefing is definitional, despite arguing to the contrary to this Court at

the hearing, (*See* Ex. B, Markman Hearing Transcript at 77); and (ii) that about means “20% of the number modified in the appropriate direction(s).”

III. THE CLAIM TERM “DOSE”

Also, in remarks filed on August 24, 2012, in the same continuation application in the ‘431 patent family, Jazz made unequivocal statements regarding the proper construction of the term “dose.” (*See* Ex. A, August 24, 2012 Amendment & Response under 37 C.F.R. § 1.111 filed in U.S. Patent Application No. 13/446,892 at 7-8.) These clear statements support Roxane’s proposed construction that “dose” should be construed as Roxane proposed in its claim construction briefs, *i.e.* the therapeutic amount of sodium oxybate that a patient actually takes, to distinguish a piece of prior art. Specifically, Jazz stated at page 7 of the August 24, 2012 Amendment & Response as follows:

Gessa et al. provides no precise disclosure of the *dose amounts* given to “alcohol dependent individuals” except in “Chemical Study 1 in which subjects were *given* 0.05 g/Kg/day “divided in *two administrations*,” page 7, lines 3-5. . . . Gessa et al. also does not disclose *dilution of a GHB syrup containing 500 mg/ml GHB to yield treatment doses*

(Ex. A at 7 (emphasis added), *cf.* D.I. 77 at 10-11.)

IV. CONCLUSION

For these reasons, Roxane respectfully requests the Court enter Exhibit A into the claim construction record and consider this supplemental evidence in making its claim construction rulings on the proper construction of “about” and “dose.”

Respectfully submitted,

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